

REMARKS

Claims 19-38 were pending in the application. Claims 1-18 were canceled by previous amendment. By this Amendment, claims 39-41 have been added to further define the invention. Support for new claims 39-41 is found in the specification (page 40, line 18 through page 42, line 2). No new matter has been added.

Applicants enclose a check in the amount of \$ 54.00 for the three additional claims in excess of twenty (20). No additional fee is believed necessary for entry and consideration of this Amendment.

The following remarks are believed to be fully responsive to the Office Action mailed June 17, 2004.

I. Claims 19-38 Fully Comply With The Written Description Requirement Of 35 U.S.C. § 112, First Paragraph.

Claims 19-38 are rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the written description requirement. (Office Action, page 2, ¶ 4).

Applicants submit that claims 19-38 fully comply with the written description requirement. (See MPEP §§ 2163 - 2163.07). The standard for determining whether the “written description” requirement of 35 U.S.C. § 112, first paragraph, has been satisfied is whether the applicant has conveyed with reasonable clarity to those skilled in the art that, as of the filing date of the application, the applicant was in possession of the invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). (See MPEP § 2163.02). “An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).” (MPEP § 2163).

As discussed below, Applicants have met this standard since the original specification adequately describes the claimed invention pursuant to 35 U.S.C. § 112, first paragraph.

Applicants disagree with the assertion in the Office Action that there “is no description in the specification of the claim 19 terms ‘substance’ and ‘electrochemiluminescence co-reactant’.” (Office Action, page 2, ¶ 4). Applicants submit that each of the terms is fully supported by the original specification in compliance with 35 U.S.C. § 112, first paragraph.

A. The Term “Substance” Is Supported by the Specification.

With respect to the term “substance,” the specification clearly describes substances falling within the scope of claim 19. Although the term “substance” may not be explicitly used (instead the term “composition” is used), one of ordinary skill in the art would readily understand that Applicants had possession of the claimed substance. As stated in the MPEP:

An objective standard for determining compliance with the written description requirement is, ‘does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.’ (Citations omitted).

* * *

The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.

(MPEP § 2163.02).

Further, Applicants note that the definition of “substance” from the American Heritage[®] Dictionary of the English Language, Fourth Edition, ©2000 by Houghton Mifflin Company is: “a material of a particular kind or constitution.” One of ordinary skill in the art would recognize the specification disclosure of a nanotube attached to a label and a co-reactant as also describing, by definition, a substance comprising this complex.

Thus, the claimed “substance” is fully supported by the specification as originally filed. However, to further the prosecution of the application, Applicants would agree to amend the claims to recite “A composition comprising” if doing so would place the application in condition for allowance.

B. The Term “Electrochemiluminescence Co-Reactant” Is Supported by the Specification.

With respect to the term “electrochemiluminescence co-reactant,” Examples 10 and 11 describe a nanotube with an ECL label (Ru(bpy)) and an ECL co-reactant (NADH) attached thereto. The specification teaches that “it is desirable to include a reductant, typically an amine or amine moiety (of a larger molecule) which can be oxidized and spontaneously decomposed to convert it into a highly reducing species.” (Specification, page 40, line 18 through page 41, line 6). One of ordinary skill in the art would readily understand the term “electrochemiluminescence co-reactant” to mean a substance that can be oxidized to a highly reducing species or reduced to form a highly oxidizing species. Accordingly, Applicants submit that the term “electrochemiluminescence co-reactant” is supported by the specification in compliance with the written description requirement.

C. The Terms “Compositions” And “Kits” Are Supported by the Specification.

With respect to the objection in the Office Action to the “compositions” and “kits” of claims 29-36, Applicants submit that the term “composition” is used throughout the specification and the term “kit” is used at page 50, lines 17-24 of the specification. Additionally, Examples 10 and 11 describe a formulation comprising the substance of claim 19 and a dehydrogenase enzyme. One of ordinary skill in the art would readily recognize that Applicants had possession of the claimed “composition” or “kit” in view of the specification as originally filed.

Accordingly, Applicants respectfully submit that there is no reasonable basis for challenging the adequacy of the written description. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). (See MPEP § 2163.04). Therefore, Applicants respectfully request that the rejection under the “written description” requirement of 35 U.S.C. § 112, first paragraph, be withdrawn.

II. Claims 19-38 Are Enabled.

Claims 19-38 are rejected under 35 U.S.C. § 112, first paragraph, because the specification purportedly does not provide enablement for a nanotube having a “co-reactant” and ECL label attached thereto. (Office Action, page 2, ¶ 5).

The first paragraph of 35 U.S.C. § 112 requires nothing more than objective enablement. Whether this is achieved by illustrative examples or by broad terminology is of no importance. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Claims should not be rejected on the ground that the specification does not support them when the terms of the claims are no broader than the broadest description of the invention in the specification and there is no reason to challenge the operativeness of the subject matter embraced by the claims. *Ex parte Altermatt*, 183 USPQ 436, 437-38 (BPAI 1974). An assertion by the Patent Office that the enabling disclosure is not commensurate with the scope of the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed. *E.g.*, *In re Dinh-Nguyen*, 181 USPQ 46, 47 (CCPA 1974).

The specification need not provide examples or specific descriptions of embodiments for the entire scope of the invention. Such details are unnecessary as they are known in the art. Detailed procedures for making and using an invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.

(MPEP § 2164). A patent does not teach, and preferably omits, what is well known in the art. *E.g., In re Buchner*, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). (*See also*, MPEP § 2164.01). “As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970).” (MPEP § 2164.01(b)).

The test for enablement “is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976).” (MPEP § 2164.01). “The fact that experimentation may be complex does not necessarily make it undue if those skilled in the art typically engage in such experimentation.” *E.g., In re Wands*, 858 F.2d 731, 77, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). (MPEP § 2164.01).

Applicants respectfully submit that one of ordinary skill in the art would be able to practice the claimed invention without undue experimentation in view of the teachings set forth in the present specification. Further, the present specification provides examples of nanotubes having ECL labels and a co-reactant attached thereto. More specifically, Examples 10 and 11 each describe a nanotube with an ECL label (Ru(bpy)) and an ECL co-reactant (NADH) attached thereto.

Although the Office Action suggests that the claims should be limited to “specific distances and types of attachments” (Office Action, page 2, ¶ 5), Applicants respectfully disagree since one of ordinary skill in the art would be able to practice the claimed invention without undue experimentation in view of the teachings set forth in the specification.

Accordingly, Applicants respectfully submit that there is no reasonable basis for asserting that the enablement provided for the claimed invention is lacking. *In re Wright*, 27 USPQ2d

1510, 1513 (Fed. Cir. 1993). (*See also*, MPEP § 2164.04). Thus, Applicants respectfully request that the enablement rejection be withdrawn.

III. Claims 19-38 Are Definite.

Claims 19-38 are rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite. (Office Action, page 3, ¶ 6).

Applicants submit that the objected-to terms in the claims comply with 35 U.S.C. § 112, second paragraph, because they are sufficiently clear and definite to one of ordinary skill in the art.

(a) With respect to the term “substance,” it is unclear what the basis is for the objection. Terms in patent claims are not too vague unless they prevent one skilled in the art from understanding, in light of the specification, what is claimed. *E.g., Andrew Corp. v. Gabriel Electronics, Inc.*, 6 USPQ2d 2010, 2013 (Fed. Cir. 1988). Applicants note that a search of the term “substance” in issued U.S. patent claims using the USPTO database yields over 39,000 hits.

The Office Action asserts that “[o]ther than containing ‘a carbon nanotube’, it is unclear what the nature and function of the remainder of the ‘substance’ are.” (Office Action, page 3, ¶ 6(a)). Claim 19, for example, recites: “A substance comprising a carbon nanotube, an electrochemiluminescence co-reactant attached to said carbon nanotube, and an electrochemiluminescent label attached to the carbon nanotube.” There is no basis set forth in the Office Action to support requiring that the claims be limited to reciting the nature and function of the remainder of the substance. As set forth in the MPEP:

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.

(MPEP § 2173.04).

Thus, it is unclear what the basis is for objecting to the term “substance.” Accordingly, Applicants respectfully urge that this aspect of the rejection be withdrawn.

(b) With respect to the term “electrochemiluminescence co-reactant,” one of ordinary skill in the art would readily understand the meaning and scope of the term when properly construed in view of the specification and what is known in the art. In the Office Action, it is asserted that “[i]n the absence of the recitation of the specific type of reaction which is to be undergone by the ‘substance’, the nature of the ‘co-reactant’ cannot be determined.” (Office Action, page 3, ¶ 6(a)). However, claim 19 recites “electrochemiluminescence co-reactant” not simply “co-reactant.” One of ordinary skill in the art would readily understand what type of reaction is involved. Applicants submit that the claims are sufficiently clear and definite to one of ordinary skill in the art when properly construed in view of the specification. As stated in MPEP §§ 2173.01 and 2173.02:

A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification. See MPEP § 2111.01. Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. (MPEP § 2173.01).

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the

examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement. (MPEP § 2173.01).

Since the term “electrochemiluminescence co-reactant” is sufficiently clear and definite in view of 35 U.S.C. § 112, second paragraph, Applicants respectfully request that this aspect of the rejection be withdrawn.

(c) With respect to the assertion in the Office Action that claim 19 “is indefinite and incomplete for the reason that the relative configuration of the ... components cannot be determined” (Office Action, page 3, ¶ 6(b)), the claim explicitly recites a carbon nanotube having an ECL label and an ECL co-reactant attached thereto. The specification teaches modifying the carbon nanotube with functional groups to allow for the attachment of the components. Thus, it is unclear what the basis is for the asserted objection.

Accordingly, Applicants respectfully urge that this aspect of the rejection be withdrawn.

(d) With respect to the objection to the use of the term “substrate” in claims 28 and 29 (Office Action, page 3, ¶ 6(c)), one of ordinary skill in the art would readily understand that the term refers to a substrate for an enzymatic reaction when the term is properly construed in view of the specification. In fact, the term used in the claim is “an enzyme and/or substrate.” Accordingly, one of ordinary skill in the art would not construe the term generically to include a solid phase such as polystyrene as suggested in the Office Action. (See Office Action, page 3, ¶ 6(c)). However, to further the prosecution of the application, Applicants would agree to amend

the claims to recite “enzyme substrate” if doing so would result in the allowance of the application.

(e) With respect to claim 28, the Office Action asserts that “the nature of the term ‘enzyme and/or substrate’ as it relates to the ‘substance’ is unclear.” (Office Action, page 3, ¶ 6(d)). Claim 28 recites:

28. A composition comprising (i) the substance of claim 19 [*i.e.*, “A substance comprising a carbon nanotube, an electrochemiluminescence co-reactant attached to said carbon nanotube, and an electrochemiluminescent label attached to said carbon nanotube”] and (ii) an enzyme and/or a substrate.

It is unclear what the basis is for the objection. The claim is directed to a composition comprising components (i) and (ii). There is no requirement that the claim be limited to describe the configuration of components (i) and (ii) since the claim is directed to a composition and therefore merely requires that it contain (i) and (ii). Examples of compositions falling within the scope of claim 28 are described in Examples 10 and 11 which describe a composition comprising the substance of claim 19 and a dehydrogenase enzyme. As MPEP § 2173.04 states: “Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971).”

Applicants respectfully submit that there is no reasonable basis for further limiting claim 28 to describe how the recited components “relate” or “are configured” relative to each other. Accordingly, Applicants respectfully request that this aspect of the rejection be withdrawn.

(f) According to the Office Action claims 37 and 38 are purportedly “incomplete for omitting essential steps, such omission amounting to a gap between the steps.” The omitted steps are purportedly: “(i) any requirement for a reaction between the ‘analyte’ and a component of the ‘composition’ which would trigger an ECL response and (ii) a step which correlates the

ECL detection with the ‘presence or amount of analyte in the sample’.” (Office Action, page 3, ¶ 6(e)). Applicants respectfully disagree.

With respect to the purported omitted steps of a “reaction between the ‘analyte’ and a component of the ‘composition’ which would trigger an ECL response,” and “correlat[ing] the ECL detection with the ‘presence or amount of analyte in the sample’,” Applicants respectfully submit that there is no reasonable basis for limiting claim 37 to require a specific reaction between the analyte and a component of the composition or for amending it to recite a specific step of correlating ECL with the amount of analyte. One of ordinary skill in the art would readily understand the meaning and scope of claims 37 and 38 when properly construed in view of the specification. As discussed above, “[b]readth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971).” (MPEP § 2173.04). Moreover, Examples 10 and 11 of the specification show certain embodiments falling within the scope of the claims. In fact, Example 10 explicitly teaches:

To use the fibril supported ECL-based biosensor, the biosensor is mixed with an aqueous solution containing a dehydrogenase and an unknown quantity of the dehydrogenase's substrate (the substrate is the analyte) or an aqueous solution containing a dehydrogenase substrate and an unknown quantity of dehydrogenase (the dehydrogenase is the analyte). After a suitable incubation time to allow the enzyme reaction to proceed and the NAD(P)⁺ or NAD(P)H immobilized on the fibrils to be reduced or oxidized, the fibrils are drawn into an ECL instrument and the ECL of the fibrils is measured. ECL measurement is carried out in a buffer that does not contain appreciable concentrations of tripropylamine (because NAD(P)⁺/NAD(P)H are tripropylamine replacements in this invention).

(Specification, pages 97-98, Example 10).

Accordingly, Applicants submit that claims 37 and 38 are sufficiently clear and definite to one of ordinary skill in the art in view of the specification. Thus, it is respectfully requested that this aspect of the rejection be withdrawn.

(g) With respect to claim 38, the Office Action asserts “it is unclear how the additional (‘further comprises’) ‘enzyme’ or ‘enzyme substrate’ functions in the context of the method of independent claim 37.” (Office Action, page 4, ¶ 6(f)). One of ordinary skill in the art would readily understand the meaning of claim 38 when properly construed in view of the specification. Moreover, Examples 10 and 11 of the specification describe assay methods of detecting the activity of dehydrogenase enzyme using a nanotube with an ECL label (Ru(bpy)) and a substrate (NAD) (which can be converted to an ECL co-reactant NADH) attached thereto. NAD is thus both a precursor for a electrochemiluminescence co-reactant and a substrate of dehydrogenase enzymes. Thus, the activity of dehydrogenase is detected by its ability to reduce/oxidize $\text{NAD(P)}^+/\text{NAD(P)H}$, which is observable by differences in the abilities of NAD(P)^+ and NAD(P)H to cause Ru(bpy) to emit electrochemiluminescence.

Applicants submit that one of ordinary skill in the art would readily understand the meaning of claim 38 when properly construed in view of the specification. Accordingly, it is respectfully requested that this aspect of the rejection also be withdrawn.

**IV. Neither U.S. Patent No. 5,866,434 or 6,362,011 Render
The Presently Claimed Subject Matter Obvious.**

**A. Claims 19-38 Are Patentable Over
Claims 1-10 of U.S. Patent No. 5,866,434.**

Claims 19-38 are rejected under the judicially created doctrine of obviousness-type double patenting as purportedly being unpatentable over claims 1-10 of U.S. Patent No. 5,866,434 (“the ‘434 patent”). (Office Action, page 4, ¶ 8).

Applicants submit that claims 1-10 of the '434 patent do not render the presently claimed subject matter obvious. Since the determination for an obviousness-type double patenting rejection is based on the comparison of the currently pending claims to the previously issued claims (*In re Berg*, 46 USPQ2d 1226 (Fed. Cir. 1998)), the relevant question for this analysis becomes:

Do claims 1-10 of the issued patent render as obvious the presently claimed subject matter relating to a substance comprising a carbon nanotube, an electrochemiluminescence co-reactant attached to said carbon nanotube, and an electrochemiluminescent label attached to the carbon nanotube?

Applicants respectfully submit that the answer is No. Since the analysis for obviousness-type double patenting parallels that of the *Graham* factors for an obviousness determination under 35 U.S.C. § 103 (*In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991)), it is respectfully submitted that an examination of the factual inquiries for determining obviousness under 35 U.S.C. § 103 confirms the conclusion that the currently pending claims are patentably distinct and nonobvious over the '434 patent claims.

Claims 19-38 are related to a "substance comprising a carbon nanotube, an electrochemiluminescence co-reactant attached to said carbon nanotube, and an electrochemiluminescent label attached to the carbon nanotube." (Independent claim 19).

Claims 1-10 of the '434 patent do not teach or suggest a substance comprising a carbon nanotube, an electrochemiluminescence co-reactant attached to said carbon nanotube, and an electrochemiluminescent label attached to the carbon nanotube as recited in pending independent claim 19. No other prior art is relied on or asserted against claims 19-38, and thus, no other scope or content of prior art is available in this analysis. Applicants respectfully submit that the '434 patent specification's teachings cannot be used as prior art in an obviousness-type double

patenting analysis with the '434 patent claims since only the disclosure of the invention claimed in the '434 patent claims may be examined. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970).

Claims 1-10 of the '434 patent fail to teach or suggest attaching both an ECL label and an ECL co-reactant to a carbon nanotube. The Office Action urges that the substance of claim 19 is "clearly inclusive of the compositions and assays of the claims of the patent. Compare, for example, the composition of instant claim 19 and claim 18 of the patent which comprises a 'graphitic nanotube' linked to both 'an electrochemiluminescent label' and an 'enzyme' (a 'co-reactant')." (Office Action, page 4, ¶ 8).

Claim 18 of the '434 patent recites:

18. A graphitic nanotube linked to at least two components selected from the group consisting of (i) an electrochemiluminescent label, (ii) an enzyme and (iii) an enzyme cofactor.

The '434 patent claim 18 does not teach or suggest a substance comprising a carbon nanotube, an electrochemiluminescence co-reactant attached to said carbon nanotube, and an electrochemiluminescent label attached to the carbon nanotube. The fact that either an enzyme or enzyme co-factor can include an ECL co-reactant does not render claim 19 of the instant application obvious since one of ordinary skill in the art would not consider an ECL co-reactant to be an obvious variant of either an enzyme or enzyme co-factor.

Therefore, present claims 19-38 are not obvious in view of the claims of the '434 patent, and thus, do not define an obvious variant of the '434 patent claims such that an obviousness-type double patenting rejection is warranted. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**B. Claims 19-38 Are Patentable Over
Claims 1-35 of U.S. Patent No. 6,362,011.**

Claims 19-38 are rejected under the judicially created doctrine of obviousness-type double patenting as purportedly being unpatentable over claims 1-35 of U.S. Patent No. 6,362,011 (“the ‘011 patent”). (Office Action, page 5, ¶ 9).

Applicants submit that the claims of the ‘011 patent do not render the presently claimed subject matter obvious. The Office Action compares “the composition of instant claim 19 and claim 5 of the patent which comprises a ‘graphitic nanotube’ linked to both ‘an electrochemiluminescence label compound’ and an ‘assay performance substance’ (a ‘co-factor’).” (Office Action, page 5, ¶ 9).

Claim 19 of the instant application recites:

19. A substance comprising a carbon nanotube, an electrochemiluminescence co-reactant attached to said carbon nanotube, and an electrochemiluminescent label attached to the carbon nanotube.

Claim 5 of the ‘011 patent recites:

5. A kit for conducting an electrochemiluminescence binding assay comprising in one or more containers:
(a) a graphitic nanotube linked to a first assay-performance substance; and
(b) a second assay-performance substance linked to an electroluminescence label compound, said label compound comprising a rare earth metal atom or a transition metal atom.

Patent claim 5 does not teach or suggest linking an ECL co-reactant to the carbon nanotube. Contrary to the suggestion in the Office Action, the term “assay-performance substance” does not render the limitation ECL co-reactant obvious. In fact, claim 2 of the ‘011 patent describes the assay performance substance as being “selected from the group consisting of: (i) specific binding partners of said analyte of interest; and (ii) added analyte of interest or added analogues of said analyte of interest that compete with said analyte of interest for binding

to a binding partner of said analyte of interest.” Accordingly, one of ordinary skill in the art would not consider an electrochemiluminescence co-reactant to be an obvious variant of an assay-performance substance.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the comments and remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome and that all the pending claims are in condition for allowance. Withdrawal of the rejections and objections asserted in the Office Action, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

No additional fee is believed necessary for entry of this Amendment. However, the Commissioner is hereby authorized to charge any additional fee to Deposit Account No. 50-0540.

Respectfully submitted,

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